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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,441	09/08/1999	Christen M. Anderson	660088.420C1	2716

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/393,441	Applicant(s) ANDERSON ET AL.	
	Examiner Sheridan K Snedden	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42,46-48,51,57 and 113-117 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42,46-48,51,57 and 113-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1653

DETAILED ACTION

1. Applicant's amendment of claims 42, 47 and 51 and addition of new claims 113-117 in paper filed 25 June 2004 is acknowledged. Claims 42, 46-48, 51, 57 and 113-117 are pending.

Withdrawal of Objections and Rejections

2. All objections and/or rejections are withdrawn in favor of the following rejections.

Maintained Rejections

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1653

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 42, 46-48, 51, 57 and 113-117 are provisionally rejected under the judicially created doctrine of double patenting over claims 42 and 46-57 of copending Application No. 09/810,644, published as US 20020012992 A1. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Current claims 42, 46-48, 51 and 57 are directed to the polypeptide ANT-3 and ANT-3 fusion proteins. This recitation of ANT-3 and ANT-3 fusion proteins overlaps the claims of said copending application. Additionally, the current claims recite the method by which the protein product is made and thus represent product by process claims. Without evidence to the contrary, the ANT-3 of copending application 09/810,644 would be identical to the ANT-3 of the product-by-process recited in the claims. Variants are also claimed in copending application 09/185,904.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

a. Applicant argue at pages 5-6 of the response that the claims are patentably distinct. This argument is deemed unpersuasive to overcome the arguments above because the claims are directed to overlapping subject matter.

5. Claims 42, 46-48, 51, 57 and 113-117 are provisionally rejected under the judicially created doctrine of double patenting over claims 42, 44, 46-51 and 57 of copending Application No. 09/185,904, published as US 20020177185 A1. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Current claims 42, 46-48, 51 and 57 are directed to the polypeptide ANT-3 and ANT-3 fusion proteins, which bind ligand and localize to membranes. This recitation of ANT-3 and ANT-3 fusion proteins overlaps the claims of said copending application. Additionally, the current claims recite the method by which the protein product is made and thus represent product by process claims. Absent evidence to the contrary, the ANT-3 of copending application 09/185,904 would be identical to the ANT-3 of the product-by-process recited in the claims. Variants are also claimed in copending application 09/185,904.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending

Art Unit: 1653

application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

b. Applicant argue at pages 5-6 of the response that the claims are patentably distinct. This argument is deemed unpersuasive to overcome the arguments above because the claims are directed to overlapping subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozens *et al.* (J Mol Biol. 1989 Mar 20;206(2):261-80) in view of Adrian *et al.* (Mol Cell Biol (1986)6(2): 626-634).

Cozens *et al.* teach a human mitochondrial ADP/ATP translocase gene encoding the ANT3 protein, which is 100% identical to the amino acid sequence of SEQ ID NO:33 (regarding claim 42). The gene taught by Cozens *et al.* encodes the mitochondrial ATP/ADP carrier and thus localizes to the mitochondria and binds to ANT ligand (addressing limitations of claim 42). The deduced amino acid sequence is given in Figure 2, which is 100% identical to the deduced sequence of SEQ ID NO: 33. Cozens *et al.* does not teach the process of producing ANT3 protein by recombinant expression. Figure 7 teaches the amino acid sequences of other mitochondrial ADP/ATP translocases, of which is the yeast ANT taught by Adrian *et al.*

Art Unit: 1653

Adrian *et al.* recombinantly expresses the ANT protein in the host cell *S. cerevisiae* using an expression construct comprising a promoter operably linked to the nucleic acid encoding the ANT polypeptide (see Methods and Materials; regarding claim 42). The yeast host cell would not express endogenous human ANT1 or human ANT2 (regarding claim 46). Adrian *et al.* do not teach a human ANT3 protein, however, the teachings provide the method in which to express the members of the ANT family of proteins.

Taken together, the above references teach a human ANT3 polypeptide 100% identical to the sequence set forth as SEQ ID NO: 33. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to recombinantly express the gene of Cozens *et al.* in order to obtain an isolated and purified ANT3 protein. The person of ordinary skill in the art would have been motivated by the teachings and suggestions of Cozens *et al.* in order to produce the ANT3 protein in a method such as the method taught by Adrian *et al.* Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

- c. Applicant's arguments at pages 7-11 of the present response have been considered. The Declaration submitted November 3 have been considered. Applicant's arguments submitted November 3, 2003 have been considered. Applicant argues that Cozens *et al.* was unable to purify or isolate the ANT3 polypeptide and therefore does not teach an isolated ANT3 polypeptide as presently claimed. Applicant argues that Cozens *et al.* has only taught the

Art Unit: 1653

deduced amino acid sequence of the ANT3 polypeptide, but not the isolated polypeptide.

These arguments have been considered but are not persuasive. Perhaps the specification provides for the novel method of making recombinant ANT3 protein, however, the ANT3 protein itself is known in the prior art, as taught by Cozens *et al.* Cozens *et al.* teach the amino acid sequence of ANT3 and that liver, skeletal muscle, heart, kidney and HeLa cells all express the ANT3 polypeptide (page 262). Thus, the ANT3 polypeptide was clearly known in the prior art. Applicant argues that the ANT3 polypeptide of Cozens *et al.* is neither isolated or recombinant. However, HeLa cells represent an isolated pool of ANT3 for which expression studies were performed. Furthermore, the meaning of recombinant provides for the parental recombination of DNA, and as such, recombinant ANT3 is present in HeLa cells.

New Rejections

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 117 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

Art Unit: 1653

of the claimed invention. The specification does not support an embodiment of ANT3 wherein one and only one amino acid has been substituted.

Conclusion

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for

Art Unit: 1653

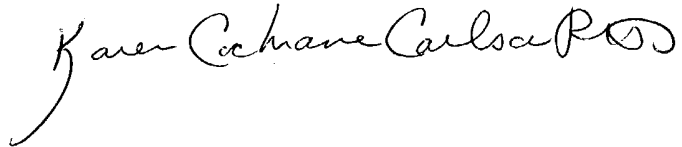
regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

August 23, 2004

SKS

A handwritten signature in cursive script that reads "Karen Cochran Carlsson" followed by a stylized monogram or initials.

KAREN COCHRAN CARLSSON, PH.D
PRIMARY EXAMINER